APR 2 4 2001

K 011081

Exactech® AcuMatch™ Integrated Hip System
M-Series Femoral Stem Component
Extra-Small Metaphyseal Segments

510(k) Summary of Safety and Effectiveness

Trade Name:	AcuMatch M-Series *Extra-Small Metaphyseal Segments*
Common Name:	Total Hip Prosthesis Femoral Component
Classification Name:	Prothesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented (Femoral Component)
Product Code:	LPH
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k)
M-Series	Exactech Inc.	#K993736
S-Rom	Joint Medical Products	
Impact	Biomet	
Mallory Head	Biomet	
Link	Link America	

The AcuMatch M-Series Extra-Small Metaphyseal segments are made of similar materials and are of a similar design to other legally marketed modular femoral components. Most notably, the proposed neck segments are equivalent in materials and design to the Exactech's predicate M-Series neck segments. M-Series components are also similar to the "S-ROM" by Joint Medical Products Corporation, the Biomet "Impact", and "Mallory-Head" and the "Link MP" by Link America.

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510(k) Summary of Safety and Effectiveness

Device Description:

Intended Use/ Indications
AcuMatch M-Series components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of the M-Series are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

The AcuMatch M-Series components are indicated for press-fit and cemented applications.

Contraindications
AcuMatch M-Series components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

Device Modifications
The device modifications presented in this "Special" 510(k) represent changes to the metaphyseal components of the original M-Series design. No changes to the distal diaphyseal segment, neck segment and locking screw components are presented in this application.

This proposed device modifications involve the addition of three sizes of "extra-small" metaphyseal segments. The new segments have smaller "flares" than the predicate M-Series design. These extra-small 'flare' components will be added in all cone diameters (21mm, 23mm, 25mm, 27mm, 29mm, and 31mm). The proximal sizing difference between all flares is constant at 4mm.

There have been no changes to materials or processes for the metaphyseal segments. Like the predicate AcuMatch M-Series metaphyseals (#K993736), the proposed components are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F1472-99.

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Performance Data Summary

Three-Point Bending Fatigue testing was conducted and compared to predicate device performance to verify that the implant performance would be adequate for anticipated *in-vivo* loading. The acceptance criteria were to produce a device with equivalent performance as compared to the cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2001

Gary J. Miller, Ph.D.
Vice President of Research and Development
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K011081
Trade/Device Name: AcuMatch M-Series Extra Small Metaphyseal Segments
Regulation Number: 888.3358
Regulatory Class: II
Product Code: LPH
Dated: April 06, 2001
Received: April 10, 2001

Dear Dr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® AcuMatch™ Integrated Hip System
M-Series Extra-Small Metaphyseal Segments

Indications for Use

510(k) Number: K011081

Device Name: **AcuMatch M-Series**
Extra-Small Metaphyseal Segments

Indications for use:

AcuMatch M-Series Femoral Components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, congenital hip dysplasia, rheumatoid arthritis, ankylosing spondylitis, and/or post-traumatic degenerative problems. M-Series components are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present.

AcuMatch M-Series components are intended to be used in press-fit and cemented applications.

Contraindications:

AcuMatch M-Series components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011081

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____